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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,066	01/29/2002	Norman Barton M.D	10793/52	2582
23838	7590	10/06/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			TRAVERS, RUSSELL S	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,066

Applicant(s)

M.D ET AL.

Examiner

Russell Travers, J.D., Ph.D

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 48-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 6-47 and 52-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's election with traverse of Group IV, claims 6-47 and 52-73 in the reply filed on August 5, 2004 is acknowledged. The traversal is on the ground(s) that no undue burden would be placed on Examiner in including all presented inventions in the current examination. This is not found persuasive because those searches required for those herein recited distinct inventions would be an undue burden: and concomitantly with the consideration of such searches for each invention, would place a crushing burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-5 and 48-51, reading on non-elected subject matter are withdrawn from consideration.

The Election filed August 5, 2004 has been received and entered into the file.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is

directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those medicaments that are “a compound” useful for practicing the invention as claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of those medicaments that are “a compound” useful for practicing the invention as claimed examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all those medicaments that are “a compound” useful for practicing the invention as claimed,

necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 6-27 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 6-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-27 are rendered indefinite by the phrase "a compound" that would be useful for practicing the invention as claimed and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining medicaments that are useful as "a compound" useful for practicing the invention as claimed are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those medicament levels that are "an amount that is less than the amount preferable for " providing some indefinite physiological effect useful for practicing the invention as claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these medicament levels without undue experimentation. In the instant case, only a limited

number of those medicaments administrations that are useful for practicing the invention as claimed examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of physiological effects envisioned. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all those medicament dose levels that are "an amount that is less than the amount preferable for " providing some indefinite physiological effect useful for practicing the invention as claimed, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 21, 27, 33, 67, 71 and 73 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 21, 27, 33, 67, 71 and 73 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, 27, 33, 67, 71 and 73 are rendered indefinite by the phrase "an amount that is less than the amount preferable for " and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining those medicament levels that are "an amount that is less than the amount preferable for " providing some indefinite physiological effect useful for practicing the invention as claimed are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Examiner notes the open-ended

language for this limitation allows for active ingredients to be administered at levels below that level required for a significant reduction a wound's healing time. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 8, 10-12, 44, 46, 47, 54, 56 and 57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 10-12, 44, 46, 47, 54, 56 and 57 are rendered indefinite by the phrase "has not recently experienced" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining those time frames that would encompass "has not recently experienced" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Examiner notes the open-ended language for this limitation allows for time frames from minutes to decades, with no guidance as to the time frame envisioned. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 52-73 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52-73 are rendered indefinite by the phrase "anabolic steroid" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Examples of those medicament compounds which would include "anabolic steroids" are

not set forth in the specification, neither individually, nor as a closed set. Absent such exemplification, the skilled artisan could not establish the identity of the required "anabolic steroid" compounds that were required to practice the invention as herein envisioned. Applicant's phrase fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 13, 24, 42, 58, 59 and 70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals & Interferences in *Ex parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303, as to where broad language is followed by "such as" and then narrow language. The Board stated, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. In the present instance, claims 13, 24, 42, 58, 59 and 70 recite the broad limitations of a disease state, and the claims also recite various factors to include, or exclude such disease states as limitations, which is a narrower statement of the range/limitation. Applicants' recitation of the broad range or limitation together with

a narrow range or limitation renders claims 13, 24, 42, 58, 59 and 70 properly rejected as indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-7, 9-21, 23-27, 29, 31-42, 45-47, 52-52, 55-67 and 69-73 are rejected under 35 U.S.C. § 102(b) as being anticipated by Morton et al.

Morton et al teach the claimed compound as useful for enhancing wound healing in normal healthy individuals upon oral administration of 100 P.P.M. oxandrolone.

Additionally, Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex*

parte Novitski, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 6-47 and 52-73 are rejected under 35 U.S.C. § 103 as being unpatentable over Morton et al and Fishbein, in view of Boris et al.

Morton et al and Fishbein teach the claimed oxandrolone compound as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for enhancing wound healing, viewed by the skilled artisan as encompassing that use herein envisioned. Claims 8, 21, 22, 25, 27, 28 33, 43, 54, 67, 71 and 73, and the primary references, differ as to:

- 1) topical employment of these medicaments,
- 2) weight of the individuals treated, and
- 3) administration levels of the medicaments.

Boris et al teach the claimed oxandrolone compound as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for providing this compounds old and well known therapeutic benefits, to include enhancing wound healing, by administering the claimed compound either sub-cutaneous, or topically, as herein claimed. Possessing these teachings the skilled artisan would have been motivated to employ the claimed compound topically and enjoy a reasonable expectation of therapeutic success.

Morton et al, Fishbein and Boris et al teach the claimed oxandrolone compound as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as and anabolic steroid, known to the skilled artisan as useful for providing this compounds old and well known therapeutic benefits: positive weight gain. Possessing these teachings the skilled

artisan would have been motivated to employ the claimed compound in individuals benefiting from weight gain and enjoy a reasonable expectation of therapeutic success.

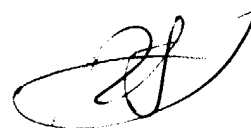
Claims 21, 25, 27, 33, 67, 71, and 73 specifically require a pharmaceutical composition containing the individual ingredients in specific physiologically related rates. Morton et al and Fishbein employed the claimed compounds at rates to effect the wound healing utility herein envisioned, not specifically reciting the physiological effects herein claimed. The skilled artisan would have seen conventional compositions useful for treating wounds, and the therapeutic administration of these compositions to treat wounds by conventional means as residing in the skilled artisan purview. Examiner additionally notes; "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" *In re Peterson*, 315 F.3d 1325 (CAFC 1003). Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview, and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the administering the claimed wound healing compositions for this old and well known use. .

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D., Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617